510k summary

K112830

NOV 13 2012

Noninvasive Medical Technologies, Inc.

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part **807**, Subpart **E**, Section **807.92.**

APPLICANT	Noninvasive Medical Technologies, Inc. 6412 S. Arville St. Las Vegas, NV 89118 Tel: (888) 906-0413 Fax: (702) 614-4170
OFFICIAL CORRESPONDENT	Dr. Marc O Griofa, M.D. (MB BCh BAO), Ph.D., F.A.W.M. Chief Technology/Medical Officer Tel: (888) 906-0413 Fax: (702) 614-4170 mogriofa@nmtinc.org
DATE PREPAIRED	October 24,2012
TRADE NAME	ZOE Fluid Status Monitor
MODEL	ZOE2B
COMMON OR CLASSIFICATION NAME	Impedance Plethysmograph
DEVICE CLASSIFICATION	Class II per 21CFR §870.2770
PRODUCT CODE	DSB
PREDICATE DEVICE NAMES	ZOE Fluid Status Monitor

The ZOE Fluid Status Monitor is substantially equivalent to the following currently marketed Predicate Device.

Manufacturer	**Device Name**	**510-K Number**	**Decision Date**
Noninvasive Medical Technologies, Inc.	ZOE Fluid Status Monitor	K042113	Sept. 14, 2004

Device Description:
The ZOE Fluid Status Monitor is a non-invasive, battery powered impedance monitor designed as an 'early warning' monitor for determining changes in the fluid status of patients with fluid management problems.

The ZOE Fluid Status Monitor works by applying a low amplitude high frequency electrical current to the body and measuring the electrical impedance. Base Impedance also known as Zo, decreases when fluid increases and increases when fluid decreases.

The ZOE Fluid Status Monitor is designed for use with disposable, self-adhesive silver / silver chloride electrodes that are readily available / commercially approved within the United States for other approved cardiovascular monitoring systems.

Labeling:
Federal (United States) Law restricts this device to sale by or on the order of a physician or licensed healthcare professional.

Indications For Use:
The ZOE Fluid Status Monitor is intended for patients:
With fluid management problems

- Taking diuretic medication
- Living with Heart Failure
- Living with End-stage Renal Disease

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- Recovering from Coronary Artery Disease related event
- Suffering from Recurrent Dehydration

This device is intended for use under the direction of a physician, for the non-invasive monitoring and management of patients with fluid management problems in a variety of medically accepted clinical applications.

Predicate Device Discussion:
The hardware utilized in the ZOE Fluid Status Monitor is identical to the hardware utilized in the currently marketed approved device the ZOE Fluid Status Monitor K042113 (September 14, 2004). The ZOE Fluid Status Monitor has the identical indications for use as the predicate devices the ZOE Fluid Status Monitor K042113 (September 14, 2004)

Performance Characteristics:
There is no performance standards published for Product Code DSB Impedance Plethysmograph (870.2770)

Quality and Safety Testing:
Noninvasive Medical Technology is presently certified to ISO13485 2003 as of 9/27/09 by IQ Net and NEMKO AS (Registration Number 908132). All products are designed and manufactured under Quality Management System. The following quality assurance measures were applied to the Zoe Fluid Status Monitor:
Risk Analysis
Requirements Review
Design reviews
Code Inspections
Verification and Validation
H/W and S/W Implementation Verification Testing

The ZOE Fluid Status Monitor underwent testing to assess the overall electrical safety and EMI safety by an independent testing house. The ZOE Fluid Status Monitor complies with the electrical standards of the Underwriters Laboratories UL 2601-1 / CSA C22.2 No. 60601 The ZOE met all electrical and electromagnetic compatibility (EMI) safety requirements, set forth in the European national Safety Requirements LVD Low voltage Directive testing to Safety of Medical Devices EN 60601-1:2003, EMC testing to Emissions / Immunity Requirements for EMC/EMI requirements for Medical Devices EN 60601-1-2 which reasonably assures the device is safe when used as directed for its prescribed intended use.

Conclusion:

The ZOE Fluid Status Monitor has the same method of operation and is functionally equivalent to the predicate device. The hardware utilized in the ZOE Fluid Status Monitor is identical to the hardware utilized in the currently marketed approved device the ZOE Fluid Status Monitor. K042113 (September 14, 2004). The ZOE Fluid Status Monitor does not raise any new issues of safety, effectiveness or performance of the device when compared to the existing predicate device ZOE Fluid Status Monitor K042113 (September 14, 2004).

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

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Noninvasive Medical Technologies, Inc.
c/o Marc O Griofa, M.D., Ph.D., F.A.W.M.
Chief Medical/Technology Officer
6412 S. Arville Street
Las Vegas, NV 89118

Re: K112830
Trade/Device Name: ZOE Fluid Status Monitor
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: Class II (two)
Product Code: DSB
Dated: October 24, 2012
Received: October 26, 2012

Dear Dr. O Griofa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

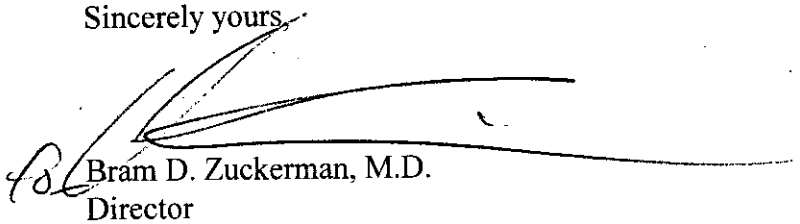
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112830

Indications for Use Statement

510(k) Number K112830

Previously Cleared as: K042113

Device Name: ZOE Fluid Status Monitor
Model Number : ZOE2b

Indications For Use:

The ZOE Fluid Status Monitor is intended for patients:

- With fluid management problems
- Taking diuretic medication
- Living with Heart Failure
- Living with End-stage Renal Disease
- Recovering from Coronary Artery Disease related event
- Suffering from Recurrent Dehydration

This device is intended for use under the direction of a physician, for the non-invasive monitoring and management of patients with fluid management problems in a variety of medically accepted clinical applications.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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